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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/005,684      | 11/08/2001  | Aristo Vojdani       | IMSC12.005A         | 9590             |

20995 7590 01/05/2004

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EXAMINER

YANG, NELSON C

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/005,684

Applicant(s)

VOJDANI, ARISTO

Examiner

Nelson Yang

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 03/15/2002. 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statement filed March 15, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The term "normal" in claim 1 is a relative term which renders the claim indefinite. The term "normal" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what levels of antibodies would be considered normal, or how the range of normal levels of antibodies would be obtained.

5. The remainder of the claims are indefinite due to their dependence on an indefinite claim.

*Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Yeaman [US 6,645,725].
8. Yeaman teaches a method for diagnosing the likelihood and severity of endometriosis in a patient by determining a level of antibodies against an autoantigen for autoimmune disease (column 4, lines 13-22), and comparing the level of antibodies with normal levels of antibodies, where normal levels of autoantigen antibodies for autoimmune disease indicate optimal conditions and higher than normal levels of autoantigen antibodies for autoimmune disease indicate ongoing pathology or prediction of early pathogenic reaction for autoimmune disease (column 4, lines 16-22).
9. With respect to claim 2, Yeaman teach a method where the autoantigen for autoimmune disease is selected from the group consisting of lupus peptides, arthritis peptides, platelet glycoprotein and immune complexes (IgA, IgG, IgM) (column 4, lines 56-58).
10. With respect to claim 3, Yeaman teaches a method of determining the level of antibodies using an assay (column 4, lines 27-39).

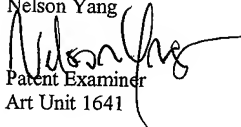
11. With respect to claim 4, Yeaman teaches a method of determining the level of antibodies using an ELISA test (column 4, lines 27-39).
12. With respect to claim 5, Yeaman teaches a method where antibodies are measured from saliva (claim 12).
13. With respect to claim 6, Yeaman teaches a method where the measured antibodies are IgA (column 4, lines 56-58).

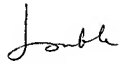
### *Conclusion*

14. No claims are allowed.
15. The following references are also cited as art of interest: Pestronk [US 5,985,578], Pestronk [US 6,020,140], Pestronk [US 6,121,004], Faustman et al [US 6,617,171], Roth [US 6,596,501], Garry et al [US 5,834,215], US Wagatsuma et al [US 5,976,810], Tobin et al [US 5,846,740], Vold et al [US 5,561,049]
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (703) 305-4508. The examiner can normally be reached on 8:30-5:00.
17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.
18. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 10/005,884<sup>6</sup>  
Art Unit: 1641

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Nelson Yang  
  
Patent Examiner  
Art Unit 1641

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
12/22/03